



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,136	02/14/2002	Ring-Ling Chien	100/13010	8859
21569	7590	05/05/2004	EXAMINER	
CALIPER LIFE SCIENCES, INC. 605 FAIRCHILD DRIVE MOUNTAIN VIEW, CA 94043-2234			ALEXANDER, LYLE	
		ART UNIT	PAPER NUMBER	
		1743		

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

15

Office Action Summary	Application No.	Applicant(s)
	10/076,136	CHIEN ET AL.
	Examiner Lyle A Alexander	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 22-31 and 37 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-3,5-21 and 32-36 is/are rejected.
- 7) Claim(s) 4 is/are objected to.
- 8) Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/27/03; 6/4/02</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____ . |

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21 and 32-36, drawn to a microfluidic system and method of use with an orthogonal detection channel, classified in class 422, subclass 102.
- II. Claims 22-31, drawn to an analytical system that permits filtration and optical analysis through a parallel conduit, classified in class 422, subclass 100.
- III. Claim 37, drawn to a method of enhancing optical sensitivity, classified in class 359.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the spatial filters attached to the body are not required. The subcombination has separate utility such as a filtration device.

Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions invention III directs light along the entire length of the first channel which is not disclosed in either inventions I,II. Furthermore, inventions I,II have different modes of operation because the optical detection is performed in the detection channel that is orthogonal to the first channel.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. McKenna on 4/30/04 a provisional election was made with traverse to prosecute the invention of group I, claims 1-21 and 332-37. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims do not identify the claim from which they are intended to depend from. For the purposes of examination, dependency from claim 15 will be assumed.

Double Patenting

Claims 1-21 and 32-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/225,454[US 2003/0036206]. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application teaches a method and apparatus having a detection channel that is orthogonal to the sample application channel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3,5-6,15-21 and 32-36 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Parce et al. (USP 6,267,858).

Patel et al. teach in col. 15 lines 47+ figure 1 comprises a series of channels(110,112), a channel(114) communicating to a reagent area(106) and a channel(110) communicating to a detection zone(116). Column 16 lines 25+ teach channel(112) is used to introduce the test compounds. Channel(112) has been read on the claimed "first channel" and is normal to channel(110) that communicates to detection zone(116). Channel(110) has been read on the claimed "detection channel". Column 17 lines 16+ teach a detection system that has been read on the claimed "detection system". Column 17 lines 12+ teach a transparent cover that has been read on the second planar substrate while the base of device(102) has been read on the first substrate.

Claims 1-3,5-6 and 32-36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wilding et al.(USP 5,928,880).

Wilding et al. teach a microfluidic system in figure 6a comprising a sample application port(56) and associated channels that has been read on the claimed "first channel segment". A detection region(117) that is orthogonal to the application port has been read on the claimed "detection channel". Column 11 lines 40+ teach the results are viewed through a transparent cover "visually or by machine". The taught transparent cover has been read on the claimed second substrate. The taught machine for viewing optical results has been read on the claimed "detection system". The fluiddevice wit

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. or Wilding et al.

Séé Parce et al. and Wilding et al. Supra.

Parce et al. teach in column 15 line 47+ the cross sectional diameters of the channels in the range of 0.1-500 micrometers. Claim 1 teaches the dimension of the channels can be different from each other. Parce et al. and Wilding et al. are silent to the claimed detection channel having a cross section area about 0.1 and 5 times the cross sectional area of at least one of the first and second channels. Parce et al. and Wilding et al. are also silent to the dimensions of the channels and volumes.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has predictable and well-known results. The relative dimension of channels and of a device area a result effective variable that have the well known and the expected results of altering fluid flow rates through the device.

The court decided In re Yount (80 USPQ 141) "... mere size ordinarily is not a matter of invention...". Additionally, the court also reiterated Yount in In re Rose (105 USPQ 237) again stating "... the size of the article under consideration is not ordinarily a matter of invention ...".

In view of the above court decisions, it would have been within the skill of the art to modify Parce et al. and have the detection channel(110/116) between 0.1 and 5 times the cross sectional area of the first channel and the length of the detection channel from about 10 microns to 1mm, as optimization of a result effective variable and also in view of Yount and Rose above. Similarly, it would have been within the skill of the art to modify Wilding et al. and have the detection channel(117) between 0.1 and 5 times the cross sectional area of the first channel and the length of the detection

channel from about 10 microns to 1mm, as optimization of a result effective variable and also in view of Yount and Rose above.

Allowable Subject Matter

Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The referenced cited by applicants in the IDS and listed on the numerous 1449's have been made of record. While the statements filed clearly do not comply with the guidelines set forth in MPEP 2004 regarding both the number of references cited and the elimination of clearly irrelevant art and marginally cumulative information, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 does not require that the information be material, rather they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references, however, the cloaking of a clearly relevant reference by inclusion in a long list of citations may not comply with Applicant's duty of disclosure, see Penn Yan Boats, inc. V. Sea Lark boats Inc., 359 F. Supp. 948, aff'd 479 F. 2d. 1338.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander
Primary Examiner
Art Unit 1743

